K102896 (1/3)

DEC 13 2010

510(k) Summary

Submitter:	Zimmer Trabecular Metal Technology, Inc. 10 Pomeroy Road Parsippany, New Jersey 07054
Contact Person:	Kathleen Rutherford Associate Director, Regulatory Affairs Telephone: (973) 576-0139 Fax: (973) 884-8792
Date:	September 30, 2010
Trade Name:	Trabecular Metal™ Tibial Cone Augments
Common Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented and uncemented
Classification Name:	"Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis"; and "Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis"
Reference:	21 CFR § 888.3560, JWH and 21 CFR § 888.3565, MBH

DEVICE DESCRIPTION

The existing, commercially available NexGen® Trabecular Metal™ Tibial Cone Augments are manufactured wholly of Trabecular Metal porous tantalum, the same material that comprises numerous medical devices intended for use in orthopedic applications. The devices which are the subject of this 510(k), the modified NexGen Trabecular Metal Tibial Cone Augments are also manufactured of the same Trabecular Metal material, using the same methods as the predicate device. The existing, commercially available NexGen Trabecular Metal Tibial Cone Augments have tapered posterior, medial and lateral walls. The periphery of the inferior surface is smaller than that of the superior surface. A similar taper pattern is also present in the modified tibial cones.

Both the modified tibial cones augments and the existing, commercially available tibial cone augments are to be used in conjunction with Zimmer's NexGen® Complete Knee Systems- both the Legacy® Constrained Condylar Knee (LCCK) Stemmed Tibial Bases and the tibial component of Zimmer's Rotating Hinge Knee (RHK) System. Fixation of all of the cone

augments to the tibial implant is accomplished by cementing the superior portion of the augment to the underside of the tibial baseplate. Apposition of the cone to bone inside the medullary canal is with or without cement when used with the LCCK tibial implant and with cement for the RHK tibial implant. With all of these tibial cone augments the LCCK tibial baseplate inferior surface must be cemented to the bone and the required stem extensions can either be cemented or press-fit.

The existing, commercially available augments come in four medium & large sizes, two height options and stepped augments. They can be used in conjunction with Zimmer's LCCK or RHK Knee Systems.

INDICATIONS FOR USE

Trabecular Metal Tibial Cone Augments are intended for use where severe degeneration, trauma, or other pathology of the knee joint indicates total knee arthroplasty. When used with the NexGen Complete Knee Solution - Rotating Hinge Knee (RHK) System, the Trabecular Metal Tibial Cone Augments are for cemented use only. When used with the NexGen Complete Knee Solution - Legacy Constrained Condylar Knee System, the Trabecular Metal Tibial Cone Augments are for cementless or cemented use.

DEVICE TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE(S)

Zimmer Trabecular Metal Technology, Inc. has submitted documentation demonstrating the substantial equivalence of the proposed implant to its predicate devices. The subject implant is identical to its predicate devices with respect to intended use/indications for use, materials, and basic principles of operation.

PERFORMANCE DATA

A comparative Finite Element Analysis (FEA) study was performed to determine whether the proposed design represented a worst case for the product line across different normal gait

activities (walking and deep flexion). The results of testing and analyses conducted demonstrate that the proposed implants adequately meet the predetermined requirements established for its mechanical performance, supporting substantial equivalence to the predicate Trabecular Metal™ Tibial Cones.

SUBSTANTIAL EQUIVALENCE

The NexGen® Trabecular Metal™ Tibial Cone Augments product line extension is the same as the predicate devices with respect to intended use/indications for use, technological characteristics and basic principles of operation. As demonstrated by supporting tests and descriptions, this product line extension does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Trabecular Metal Technology
% Ms. Kathleen Rutherford
10 Pomeroy Road
Parsippany, New Jersey 07054

DEC 13 2010

Re: K102896
Trade/Device Name: Zimmer Trabecular Metal™ Tibial Cone Augments
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: September 30, 2010
Received: September 30, 2010

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 13 2010

510(k) Number (if known): K102896

Device Name: Trabecular Metal Tibial Cone Augment

Indications for Use:

Trabecular Metal Tibial Cone Augments are intended for use where severe degeneration, trauma, or other pathology of the knee joint indicates total knee arthroplasty. When used with the NexGen Complete Knee Solution - Rotating Hinge Knee (RHK) System, the Trabecular Metal Tibial Cone Augments are for cemented use only. When used with the NexGen Complete Knee Solution - Legacy Constrained Condylar Knee System, the Trabecular Metal Tibial Cone Augments are for cementless or cemented use.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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for M. Mulkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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